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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,198	10/26/2001	Peter M. Lloyd	0208.00006.01R	1707

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EXAMINER
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MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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03/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/057,198	<b>Applicant(s)</b> LLOYD ET AL.	
	<b>Examiner</b> MICHAEL G. MENDOZA	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/4/2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,10,13,19,29-34,45 and 84-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,10,13,19,29-34,45 and 84-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                                   |                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/30/07, 1/15/08, 3/21/08</u> | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Response to Arguments***

1. After further consideration the examiner has seen that the prior art reference of Counts et al. 5060671 does in fact read on the limitations of the claims. The examiner draws the applicant's attention to col. 7, lines 23-46, where Counts et al. teaches a heater that moves. Since the heater moves while heating, it would be generating a moving heating zone.
2. The indicated allowability of claims 1, 4-8, 10, 13, 19, 29-34, 45, and 84-91 is withdrawn.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 7, 8, 10, 13, 19, 32-34, 45, 84, 88-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Counts et al. 5060671.
5. Counts teach a method for delivering a physiologically active compound to a patient comprising the steps of: providing a substrate having first and second ends upon which a physiologically active compound has been deposited; generating a moving heating zone that traverses at least a portion of the substrate in a direction from the first end of the second end, thereby sequentially heating compound exposed to the heating zone to produce a vapor (col. 7, lines 23-26); allowing the vapor to condense to

Art Unit: 3734

form an aerosol; and administering the resulting aerosol to a patient; defining a compound deposition area; moving a heating zone with respect to the compound deposition area to progressively vaporize compound exposed to the heating zone (col. 7, lines 23-46); allowing the vapor to condense to form an aerosol (it would be inherent the vapor produced by Counts et al. condenses if the end product is an aerosol); administering the resulting aerosol to a patient; wherein the heating of the compound to form a vapor occurs over a period of 2 seconds or less (col. 5, lines 30-41); wherein the vapor is free of excipients (Counts et al. states that glycerine or water can be added, if not added the compound would be excipient free)

6. As to claim 34, Counts et al. teach the use of the same or similar compounds (nicotine). Those compounds would inherently have the same physical and chemical properties. Therefore the compounds as taught by Counts et al. would inherently vaporized with less than 2%.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 4, 29, 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Counts et al.

9. Counts et al. fails to specifically teach wherein the coating thickness is less than 10  $\mu\text{m}$ . Counts et al. does however teach coating a substrate with a compound. The

Art Unit: 3734

Applicant has not disclosed that claimed thickness of the coating provides an advantage, is used for a particular purpose, or solves a stated problem. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

10. Claims 5, 6, 30, 31, 86, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Counts et al. as applied to claims above, and further in view of Rabinowitz et al. 6783753.

11. Counts et al. teaches the method of claim 19. It should be noted that Counts et al. fails to teach where the aerosol has a mass median aerodynamic diameter of between 1-3  $\mu\text{m}$  or 10-100 nm.

12. Rabinowitz teaches an aerosol that has a mass median aerodynamic diameter of between 1-3  $\mu\text{m}$  or 10-100 nm (col. 3, lines 30-39). Furthermore, it is well known to use the claimed range for aerosols to insure deep inhalation of treatment into the lungs and to prevent sticking of aerosol to delivery devices. Therefore, it would have been obvious for one having ordinary skill in the art at the time the invention was made to use the claimed range to delivering treatment to the lungs of a patient.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is

Art Unit: 3734

(571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./  
Examiner, Art Unit 3734

***/Todd E Manahan/***

***Supervisory Patent Examiner, Art Unit 3734***